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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/590,435

08/23/2006

Paul Fraser

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27155

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11/08/2010

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CANADA

EXAMINER

BALLARD, KIMBERLY

ART UNIT

PAPER NUMBER

1649

MAIL DATE

DELIVERY MODE

11/08/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/590,435	FRASER, PAUL	
	Examiner	Art Unit	
	Kimberly Ballard	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,9-11,13-16 and 62-64 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,9-11,13-16 and 62-64 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Status of Application, Amendments, and/or Claims

1. In view of Applicant's after-final amendments and response filed October 14, 2010, the finality of the previous office action is withdrawn.
2. Claims 1, 3, 9, 11 and 62 have been amended, claims 32-35, 40-50 and 57-61 have been canceled, and new claim 64 has been added as requested in the after-final amendment filed October 14, 2010. Following the amendment, claims **1-3, 9-11, 13-16** and **62-64** are pending and under examination in the current office action.

Withdrawn Claim Rejections

3. The rejection of claims 1-3, 9-11, 13-16 and 62-63 under 35 USC 102(b) as being anticipated by US 2001/0119926 to Fraser, is withdrawn in view of Applicant's amendments to the claims. Fraser does not teach or reasonably suggest a tripeptide consisting of ANX or ANF.
4. The rejection of claims 1 and 13-15 under 35 USC 102(b) as being anticipated by US 4,426,324 to Meienhofer, is withdrawn in view of Applicant's amendments to the claims.
5. The rejection of claims 1 and 13-15 under 35 USC 102(e) as being anticipated by US 7,056,889 to Villanueva et al., is withdrawn in view of Applicant's amendments to the claims.

New Claim Objections and Rejections

Claim Objections

6. Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In the instant case, as amended claim 9 now recites the same limitations that are already present in independent claim 1.

7. Applicant is advised that should claims 1-3, 15 and 64 be found allowable, claims 9-11, 16, 62 and 63 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims

are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 1-3, 9-11, 13-16 and 62-64 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of copending Application No. 12/905,773. Although the conflicting claims are not identical, they are not patentably distinct from each other because in each case the claims recite an antifibrillogenic agent consisting of peptide ANX, wherein X is any

amino acid except cysteine, or wherein the peptide is ANF, and compositions thereof.

Therefore, the claims of the '773 application render obvious the current claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 9 and 13-16 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2008/0090770 A1 by Belmares et al.

Belmares et al. disclose peptide agents of the formula $X^1\text{-aa}^2\text{-aa}^1\text{-aa}^0$, wherein X^1 may be 0 amino acids and residues $\text{aa}^2\text{-aa}^1\text{-aa}^0$ may be ANL (SEQ ID NO: 20) (see [0073]). Therefore, Belmares teaches a peptide consisting of ANL, which meets the limitation of a peptide consisting of ANX wherein X is any amino acid except cysteine. Because the peptide ANL meets the structural limitations of claim 1, it would be expected to inherently possess antifibrillogenic and/or cytoprotective activities as recited in the claims. A chemical composition and its properties are inseparable (*In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963)), as are their processes and yields (*In re*

Von Schickh, 362 F.2d 821, 150 USPQ 300 (CCPA 1966)). Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

Belmares et al. also teach that the peptides of the invention may be formulated as pharmaceutical compositions for administration to a patient, which would include a pharmaceutically acceptable carrier (see [0110], [0113] and [0115]), thus addressing present claim 15. Accordingly, the teachings of Belmares et al. anticipate the presently recited invention of claims 1, 9 and 13-16.

12. Claims 1-3, 9-11, 13-16 and 62-64 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2005/0020809 A1 by Gazit.

Gazit teaches a peptide sequence of ANFAV (SEQ ID NOs: 126 and 127), wherein the peptide is at least 2 and no more than 15 amino acid residues in length (see pp. 53-54, and claim 24 at p. 54). Gazit further discloses that the peptide is at least 3 amino acid residues in length (see claim 21 at p. 54), and is comprised within a pharmaceutical composition (see claim 68 at p. 55). Taken together, these teachings provide for a peptide derived from ANFAV which is 3 amino acids in length, and would include the peptide consisting of ANF, and pharmaceutical compositions thereof. See MPEP § 2131, which states:

When the compound is not specifically named, but instead it is necessary to select portions of teachings within a reference and combine them, e.g., select various substituents from a list of alternatives given for placement at specific sites on a generic chemical formula to arrive at a specific composition, anticipation can only be found if the

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classes of substituents are sufficiently limited or well delineated. *Ex parte A*, 17 USPQ2d 1716 (Bd. Pat. App. & Inter. 1990). If one of ordinary skill in the art is able to “at once envisage” the specific compound within the generic chemical formula, the compound is anticipated. One of ordinary skill in the art must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be “at once envisaged.” One may look to the preferred embodiments to determine which compounds can be anticipated. *In re Petering*, 301 F.2d 676, 133 USPQ 275 (CCPA 1962).

In *In re Schauman*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978), claims to a specific compound were anticipated because the prior art taught a generic formula embracing a limited number of compounds closely related to each other in structure and the properties possessed by the compound class of the prior art was that disclosed for the claimed compound. The broad generic formula seemed to describe an infinite number of compounds but claim 1 was limited to a structure with only one variable substituent R. This substituent was limited to low alkyl radicals. One of ordinary skill in the art would at once envisage the subject matter within claim 1 of the reference.

Additionally, Gazit indicates that the peptides can be used in the treatment of an amyloid associated disease (see claims 34 and 43 at pp. 54-55), which would evidence their suitability as antifibrillogenic and/or cytoprotective agents. Therefore, one of ordinary skill in the art would be able to “at once envisage” the limited number of peptides derived from the peptide ANFAV that are at least 3 amino acids (i.e., ANF, NFA, FAV, ANFA, NFAV), and thus the teaching of Gazit are anticipatory for the presently recited invention of claims 1-3, 9-11, 13-16 and 62-64.

Conclusion

13. No claims are allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Ballard whose telephone number is 571-272-2150. The examiner can normally be reached on Monday-Friday 8:30 AM - 5 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kimberly Ballard

Art Unit 1649

/Daniel E Kolker/

Primary Examiner, Art Unit 1649

November 7, 2010